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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,301	07/27/2001	Roberto A. Macina	DEX-0188	8552
32800	7590	12/05/2005		
LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			EXAMINER TUNGATURTHI, PARITHOSH K	
			ART UNIT	PAPER NUMBER

1643

DATE MAILED: 12/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,301	MACINA, ROBERTO A.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10.11.2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11-15, 17-19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11-15, 17-19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed on 10/11/2005 is acknowledged.
2. Claims 2-10, 16, 20 and 24 have been cancelled.
3. Claims 1, 11-15, 17-19 and 21-23 are under examination.
4. The text of those sections of title 35, USC Code not included on the Office Action can be found in a prior Office Action.
5. This Office Action contains New Grounds of Rejection.

Response to Arguments

5. The rejection of Claims 1 and 11-24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as invention is withdrawn in view of the amendments to the claims.
6. The rejection of claims 1, 11-13, 16, 17, 20, 21 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Billing-Medel (U.S. Patent 6,183,952; issued February 6th, 2001) is withdrawn in view of the amendments to the claims.
7. The rejection of Claims 1, 11-15, 17-19 and 21-23, under 35 U.S.C. 102(e) as being anticipated over Lehrer (US 2002/0034739, filed July 7, 1998) is maintained ~~is~~ ¹⁰⁴ and made ~~is~~ again.

The arguments presented by the applicant in the response filed on 10/11/2005, on page 7, in regard to the 102(e) rejection have been carefully considered, but not have been found persuasive to overcome the rejection.

The applicant states that the amendment to claim 1 to be drawn to measurement in cells or tissues places the claims in condition for allowance. In response to this, Lehrer et al teach the methods of detection of metastasis of prostate, uterine or ovarian cancer comprising the detection of Lipophilin B (the same as ESBII polypeptide) in the cells and tissue in addition to the bodily fluid such as blood (paragraph 0029 and 0032). For example, paragraph 0029 states that "Metastases of carcinomas of hormonally responsive and/or hormonally regulated tissue such as uterus, ovary, prostate, testis, breast, kidney and thymus can be determined by virtue of the expression by cells of these tumors of the gene encoding one or more of the human lipophilins against a background of hematopoietic cells that does not result in the expression of these genes" and further show the expression of Lipophilin A, B and C in various tissues including Uterus, Ovarian and Prostate (Figures 11A and B).

Thus, the rejection of Claims 1, 11-15, 17-19 and 21-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Lehrer.

Conclusions

11. No claims are allowed

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi, Ph.D.
Ph: (571) 272-8789



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER